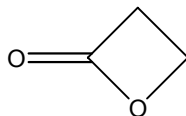


β-PROPIOLACTONE

CAS No. 57-57-8

First Listed in the *Second Annual Report on Carcinogens*



CARCINOGENICITY

β-Propiolactone is *reasonably anticipated to be a human carcinogen* based on sufficient evidence of carcinogenicity in experimental animals (IARC V.4, 1974). When administered by gavage, β-propiolactone induced squamous cell carcinomas of the forestomach in female rats. When applied topically, β-propiolactone induced papillomas that underwent a malignant change to squamous cell carcinomas in mice and papillomas, melanomas, keratoacanthomas, and squamous cell carcinomas of the skin in male hamsters. When administered by subcutaneous injection, β-propiolactone induced injection-site sarcomas in mice and rats of both sexes and fibrosarcomas, adenocarcinomas, and squamous cell carcinomas in female mice. A single intraperitoneal injection of β-propiolactone induced lymphomas in mice of both sexes and hepatomas in male mice. Keratoacanthomas and one melanoma developed in guinea pigs that received skin applications of β-propiolactone. However, the significance of these results is questionable because no controls were included in this study.

There are no data available to evaluate the carcinogenicity of β-propiolactone in humans (IARC V.4, 1974).

PROPERTIES

β-Propiolactone is a colorless liquid with a slightly sweetish odor. β-Propiolactone polymerizes on standing at room temperature. It is soluble in water and miscible with ethanol, acetone, ether, and chloroform. It is slowly hydrolyzed by water. It decomposes on standing at room temperature. When heated to decomposition, it emits acrid smoke and fumes. β-Propiolactone is available in a grade containing 97% minimum active ingredient. It reacts with alcohol, amino acids, and cysteine. It is incompatible with strong oxidizing agents and strong bases.

USE

β-Propiolactone was once a commercially important industrial chemical. At one time, more than 85% of β-propiolactone produced in the United States was used captively to manufacture acrylic acid and esters; however, it has been replaced by other more efficient and less expensive methods (Kirk-Othmer V.1, 1978). β-Propiolactone is now used for vaccines, tissue grafts, surgical instruments, and enzymes; as a sterilant of blood plasma, water, milk, and nutrient broth; and as a vapor-phase disinfectant in enclosed spaces. Its sporicidal action is used against vegetative bacteria, pathogenic fungi, and viruses (Kirk-Othmer V.7, 1979). In industry, it is used in the production of haloquinones and for polyesters used for polymer blends of polyvinyl chloride (PVC) (Kirk-Othmer V.18, 1982; Kirk-Othmer V.19, 1982).

PRODUCTION

Chem Sources listed two bulk suppliers among the twelve overall domestic suppliers of β-propiolactone identified in 1990 (Chem Sources, 1991). Chem Sources International directory identified five domestic suppliers of β-propiolactone for 1988 and 1989 (Chem Sources International, 1988). The Chem Sources USA directory identified one producer and nine suppliers of β-propiolactone in 1986 (Chem Sources, 1986). One U.S. company produced β-propiolactone from 1958 until at least 1973 (IARC V.4, 1974). No other production data were found. The 1979 TSCA Inventory identified one importer of β-propiolactone in 1977, but no volume was given (TSCA, 1979). β-Propiolactone was first produced commercially in the United States in 1958 (IARC V.4, 1974).

EXPOSURE

The primary routes of potential human exposure to β-propiolactone are inhalation, ingestion, and dermal contact. If released to water it will hydrolyze (half-life 3.5 hours). In atmosphere, it will be relatively persistent as a gas. OSHA estimated that 450 workers were possibly exposed to β-propiolactone in the workplace. Personnel at greatest risk of possible exposure included disinfectant workers and makers of virucidal agents, acrylic plastics, and resins. Potential exposure to waste effluents from production and manufacturing plants was minimal because of β-propiolactone's short half-life in water (IARC V.4, 1974). The ACGIH has set a threshold limit value for exposure to β-propiolactone in the workplace at 0.5 ppm, as an 8-hr time-weighted average (TWA). ACGIH has noted the potential contribution to overall exposure by the cutaneous route, including mucous membranes and eyes, either by airborne, or more particularly, by direct contact with the substance (ACGIH, 1986). Potential exposure occurs from use of pharmaceuticals containing β-propiolactone, e.g., in vaccines and for tissue grafts. Health professionals (e.g., physicians, nurses, pharmacists) could possibly be exposed during preparation and administration of the pharmaceuticals. Workers involved in the formulation of the products may also be exposed to β-propiolactone. The possibility of exposure also exists from contact with sterilized instruments, from ingestion of liquids sterilized with the compound, or from transfusions of blood plasma sterilized with it.

REGULATIONS

EPA regulates β-propiolactone under the Superfund Amendments and Reauthorization Act (SARA), subjecting it to reporting requirements and mandating that emergency response plans be prepared if the threshold planning quantity of 500 lb is reached. EPA has proposed handling and report/recordkeeping requirements for β-propiolactone under the Resource Conservation and Recovery Act (RCRA). OSHA regulates β-propiolactone on the basis of its carcinogenicity in animals under the Occupational Safety and Health Act (OSH Act). The regulation requires protective clothing, use of respirators, training in hygiene, medical surveillance, engineering controls to limit contamination, sign requirements for posting in regulated areas, and labeling requirements for containers. OSHA also regulates β-propiolactone as a chemical hazard in laboratories and under the Hazard Communication Standard. Regulations are summarized in Volume II, Table B-128.